

REMARKS

The Office Action of March 18, 2004, has been received and reviewed. Claims 1-21 and 23-37 are currently pending in the application. Claims 1-21, 23, 25-35 and 37 stand rejected, and claims 24 and 36 stand objected to as being dependent on a rejected base claim and being allowable if rewritten into independent form. Claims 8, 27 and 35 have been amended as set forth herein. No new matter has been added. All amendments are made without prejudice or disclaimer. Reconsideration is requested.

Rejections under 35 U.S.C. § 102

Claims 1-11, 13, 17-21, 23 and 25-35 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Roberts et al. Applicant respectfully traverses the rejection.

Independent claim 1 cannot be anticipated since Roberts et al. does not expressly or inherently disclose each and every element of claim 1. (*See, Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). Claim 1 is directed to an electrotransport device for transporting molecules of a beneficial agent from a reservoir across a semipermeable membrane and into an ionic fluid comprising, *inter alia*, a first compartment including a first electroactive material configured as a first electrode and a second electrode comprising a second electroactive material in communication with the ionic fluid, wherein the first electroactive material is electropositive or electronegative and wherein the second electroactive material is electronegative or electropositive, respectively, such that when electrically connected with the conductor and the ionic fluid, **a battery is formed**.

The Office Action asserted “as Robert’s device has the same structure as that claimed by applicant, and must therefore be capable of performing the same function.” (Office Action, page 2). “In relying upon the theory of inherency, the examiner must provide a **basis in fact and/or technical reasoning** to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” (M.P.E.P. § 2112, *citing Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis added)). Applicant respectfully submits that the Office Action does not provide a basis in fact or technical

reasoning in indicating that Robert et al.'s device would perform the same function as the electrotransport device of claim 1.

In fact, since Roberts et al. discloses that "said first and second electrodes are each electrically connected to a power source [*i.e.*, a battery]" and Roberts et al. is silent with respect to the elements of the electrotransport device of claim 1 forming a battery, no rationale exists to support the inference that the structure disclosed in Roberts et al. is capable of performing the same function as the electrotransport device of claim 1 as asserted in the Office Action. (Roberts et al., Col. 3, lines 38-40). Thus, since Roberts et al. does not identically disclose each and every element of claim 1, claim 1 cannot be anticipated.

Claims 2-11, 13 and 17 are not anticipated, at the very least, as depending from novel independent claim 1.

With further regard to claim 5, it cannot be anticipated since Roberts et al. does not expressly or inherently describe the first semipermeable membrane configured to conduct charged species from the first electrode when implanted under a subject's skin surface **in whom the electrotransport device has been implanted** as recited in claim 5. In fact, Roberts et al. does not disclose any device that is implanted under a subject's skin. (*See generally, Id.*). Thus, claim 5 cannot be anticipated.

Dependent claim 13 cannot be anticipated since Roberts et al. does not expressly or inherently describe the electrotransport device comprising a second semipermeable membrane disposed adjacently under at least a portion of the second compartment, the second semipermeable membrane configured to be in fluid communication with a second beneficial agent contained in the second compartment, the second semipermeable membrane adapted to be implanted under at least a portion of a subject's stratum corneum in whom the **electrotransport device has been implanted**. Since Roberts et al. does not disclose any device implanted under the skin of a subject, claim 13 cannot be anticipated.

Claim 17 cannot be anticipated since Roberts et al. does not identically disclose the electrotransport device having at least a portion of the first semipermeable membrane comprising **a material configured to be resorbable by a subject's body tissues in whom the electrotransport device has been implanted**. In fact, Roberts et al. does not

disclose any device implanted under the skin of a subject or a material of a semipermeable membrane that can be reabsorbed by a subject's body tissues. Thus, claim 17 cannot be anticipated.

Independent claim 18 cannot be anticipated since Roberts et al. does not expressly or inherently disclose each and every element of claim 18. For instance, Roberts et al. does not identically disclose an electrotransport device for delivering molecules of a beneficial agent to tissue of a subject **upon implantation** comprising, *inter alia*, a semipermeable membrane disposed adjacently under the at least one reservoir, the semipermeable membrane adapted to be implanted under at least a portion of the tissue of a subject, wherein a subject's tissue completes a circuit between the plurality of mutually spaced apart electrodes upon implantation under the subject's skin surface and enables delivery of molecules of the beneficial agent to the subject as recited by independent claim 18.

The device for iontophoretic delivery of Roberts et al. is not configured for implantation as recited in independent claim 18. Rather, as stated in Roberts et al. "electrodes 27 and 28 may comprise a needle electrode, static probe, micro dialysis tubing or probe, conventional surface electrode, any surgically implanted electrode or conducting material introduced into the tissue on its surface or on the outside of the body." (Roberts et al. at Col. 6, lines 57-61). Since Roberts et al. fails to identically disclose each and every element of claim 18, it cannot be anticipated.

Dependent claims 19-21, 23 and 25-26 are not anticipated, at the very least, as depending from novel independent claim 18.

Independent claim 27 cannot be anticipated since Roberts et al. does not expressly or inherently disclose a method of electrically facilitating the transport of a beneficial agent to a body tissue of a subject, the method comprising, *inter alia*, implanting at least a portion of the at least one semipermeable membrane beneath a subject's stratum corneum skin layer, wherein, **responsive to the implanting, a circuit is completed between the plurality of electrodes, thus transmitting a voltage** from the plurality of electrodes and the at least one semipermeable membrane to the body tissues. Roberts et al. does not identically disclose a voltage being transmitted responsive to implanting a semipermeable membrane, but rather is limited to the use of a power source to complete a circuit and deliver an active substance to tissue. (*See, Id.* at Col. 3, lines 36-40, Col. 6, lines 65-67 and claim 1). Thus, Roberts et al. cannot anticipate claim 27.

Dependent claims 28-34 are not anticipated, at the very least, as depending from novel independent claim 27.

With further regard to claim 31, it cannot be anticipated since Roberts et al. does not expressly or inherently describe **electrostatically repelling** the beneficial agent through the at least one semipermeable membrane. Thus, Roberts et al. cannot anticipate claim 31.

Claim 32 cannot be anticipated since Roberts et al. does not expressly or inherently describe **implanting the electrodes and the beneficial agent reservoir** under a skin surface of the subject. Roberts et al. is limited to inserting an electrode and, thus, does not identically disclose implanting a beneficial agent reservoir as recited in claim 32. Accordingly, claim 32 cannot be anticipated.

Dependent claim 34 cannot be anticipated since Roberts et al. does not expressly or inherently disclose **implanting a bottom-most surface of the at least one impermeable membrane to a depth approximating about 20-100 µm below the stratum corneum skin layer**. Thus, claim 34 cannot be anticipated.

Roberts et al. also cannot anticipate independent claim 35 since Roberts et al. does not expressly or inherently describe an intraocular delivery device for delivering a beneficial agent to a subject's eye comprising, *inter alia*, a first electrode in fluid communication with the membrane and the beneficial agent, the first electrode comprising a first electroactive material; and a second electrode comprising a second electroactive material, the second electrode configured to be in fluid communication with the subject's conjunctiva, but, except for conductive material connecting the first and second electrodes, electrically isolated from the first electrode, the first and second electroactive materials being selected, when configured together as a circuit, **to form a battery**.

As previously established herein, Roberts et al. is silent with respect to the elements of an iontophoretic device of claim 35 that form a battery. Since Roberts et al. does not identically disclose the intraocular delivery device of claim 35, claim 35 cannot be anticipated.

Claims 36 and 37 are not anticipated, at the very least, as depending from novel independent claim 35.

Reconsideration and withdrawal of the anticipation rejections of claims 1-11, 13, 17-21, 23 and 25-35 are requested.

Rejections under 35 U.S.C. § 103

Claim 12

Claim 12 stands rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Roberts et al. in view of Haak et al. Applicant respectfully traverses the rejection.

Claim 12 is nonobvious, at the very least, as depending from nonobvious independent claim 1. (*See, In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)). Further, Roberts et al. does not alone or in combination with Haak et al. teach or suggest each and every element of claim 12 as required to establish a *prima facie* case of obviousness. For instance, as claim 12 indirectly depends from claim 1 and Roberts et al. does not teach or suggest the formation of a battery as recited in claim 1, a resultant combination of Haak et al. with Roberts et al. does not teach or suggest each and every element of claim 12.

Reconsideration and withdrawal of the obviousness rejection of claim 12 are requested.

Claims 14-16 and 37

Claims 14-16 and 37 stand rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Roberts et al. in view of Theeuwes et al. Applicant respectfully traverses the rejection.

Claims 14-16 and 37 are nonobvious, at the very least, as depending from nonobvious independent claims 1 and 35, respectively. (*See, Id.*). Further, as claims 14-16 depend from claim 1 and Roberts et al. does not teach or suggest each and every element of claim 1, the combined teachings of Roberts et al. with Theeuwes et al. also fail to teach or suggest each and every element of claim 1. Thus, a *prima facie* case of obviousness cannot be established for any of claims 14-16.

Further, since claim 37 depends from claim 35 and Roberts et al. does not teach or suggest each and every element of claim 35, the combined teachings of Roberts et al. and Theeuwes et al. also fail to teach or suggest each and every element of claim 37 as required to establish a *prima facie* case of obviousness.

Reconsideration and withdrawal of the obviousness rejections of claims 14-16 and 37 are requested.

CONCLUSION

In view of the remarks presented herein, the applicant respectfully submits that the pending claims are now in condition for allowance and an early notice thereof is requested. Should questions exist after consideration of the foregoing, the Office is kindly requested to contact the applicant's attorney at the address or telephone number given herein.

Respectfully submitted,



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